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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/459,385	12/02/1999	STUART D. EDWARDS	10390-0002-2	1074

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 07/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/459,385

Applicant(s)

EDWARDS ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Applicant's amendments of February 15, 2002 have been entered and considered by the examiner. In particular, the additional figures and description has obviated the priority concerns. It is noted that the additional figures and description have been properly incorporated by reference in the parent application. Further, applicant's Terminal Disclaimer has obviated the double patenting concerns.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 33 is rejected under 35 U.S.C. 102(b) as being anticipated by Rydell ('908).

The Rydell probe system includes an elongate member (12), an electrode deployment device located within the elongate member, a retractable electrode (42) which is inserted into tissue with a radius of curvature, and a handle member for supporting the elongate member and deployment device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Abele et al ('311) or Durgin, Jr et al ('222) in view of the teaching of Rydell ('908).

Abele et al discloses a probe system including an elongate member (20), a handle (17,18) at the proximal end, an electrode deployment means located in the elongate member to advance the electrode into tissue. The only feature not expressly taught by Abele et al is the curvature of the needle.

Similarly, Durgin, Jr et al disclose a device comprising an elongate member (10) with a handle and an advancement means located in the elongate member. There is also a retractable electrode (67) which is advanced into tissue and may be retracted into the elongate member. The only feature not expressly taught by Durgin, Jr et al is a needle having curvature.

As addressed in the 35 USC 102 rejection, Rydell provides a probe which is very similar to the Abele et al and Durgin, Jr et al devices. In particular, Rydell teaches that it is known to provide the retractable needle electrode with curvature so that it may be deployed into tissue.

To have provided either the Abele et al or the Durgin, Jr devices with a curved electrode for penetration of tissue would have been an obvious design consideration for one of ordinary skill in the art in view of the teaching of Rydell.

Response to Arguments

Applicant's arguments filed February 15, 2002 have been fully considered but they are not persuasive.

With regard to the Rydell reference, applicant contends that Rydell fails to disclose an electrode having a non-deployed state when positioned in the elongate member, and a distended deployed state when advanced from the elongate member. Applicant asserts that Figure 4 shows the electrode housed within the elongate member in the same shape as when it is deployed. The examiner disagrees with applicant's interpretation of Figure 4.

The "bent wire" shown within the elongate member in Figure 4 is not the same as the deployed electrode. Figure 4 shows electrical lead (44) which is in a bent configuration. This lead is connected to electrode (50). Another lead (56) is housed within the same lumen and is connected to electrode (52). See column 4, lines 1-38. Lead (32) is connected to electrode (42) which is advanced from the elongate member. As can clearly be seen in Figure 4, electrode (42) when advanced from the elongate member (with curvature) has a cross section which would be impossible to be contained within the lumen. That is, if one were to draw an imaginary line extending along lead (32) beyond the distal end of the elongate member, the distance of deflection of the electrode (42) is a distance much greater than the diameter of the lumen. Hence, the electrode could not be contained within the lumen in the same conformation as when it is deployed.

With regard to the radius of curvature, the examiner maintains that the Rydell electrode is clearly advanced with a radius of curvature. That the curvature may be imposed by an opening in the catheter (as opposed to being formed in the electrode) is irrelevant because the claim language does not specify that the curvature is a result of shape memory, only that there is a radius of curvature.

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These arguments carry through to the 35 USC 103 rejections. The examiner maintains that Abele et al and Durgin, Jr et al clearly disclose advanceable needle electrodes, and that Rydell provides sufficient suggestion that these electrodes may be advance with curvature into tissue off-axis from the longitudinal axis of the elongate member. For these reasons, the rejections are deemed tenable and are made final.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

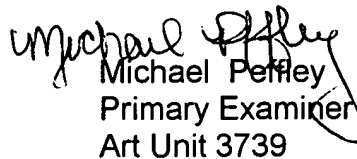
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is

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(703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Michael Perley
Primary Examiner
Art Unit 3739

mp.
July 24, 2002